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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,371	09/17/2003	Jorge L. Orbay	JGPAT03a03US	4572

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GORDON & JACOBSON, P.C.
60 LONG RIDGE ROAD
SUITE 407
STAMFORD, CT 06902

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	**PAPER NUMBER**
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,371	ORBAY, JORGE L.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,38,40-43,45-55,58-61 and 65-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,38,40-43,45-55,58-61 and 65-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/18/07* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 45 is objected to because it depends from a canceled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-38, 40-43 and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "at least one first alignment hole having a distalmost point defining a distal tangent line which is not displaced distally relative to a distal tangent line defined between said two respective peg holes" is deemed to be new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 37-38, 40-43 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 37, the limitation, "at least one first alignment hole having a distalmost point defining a distal tangent line..." renders the claim indefinite since it is unclear where this "distalmost point" is.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-38, 45-48, 51 and 53-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Weaver et al. (US 6,623,486).

Weaver et al. disclose a bone fixation plate 80 including: a head angled relative to a the shaft; the head portion defining a first set of threaded holes 86b; alignment holes much smaller in diameter than the threaded holes for provisional fixation of the bone plate; a second alignment hole 88; and a plurality of screw holes 86a in the shaft of the bone plate (Figs. 20-26, col. 6, lines 58-67 and col. 7, lines 1-17). See marked up Fig. 21 from Weaver et al. below.

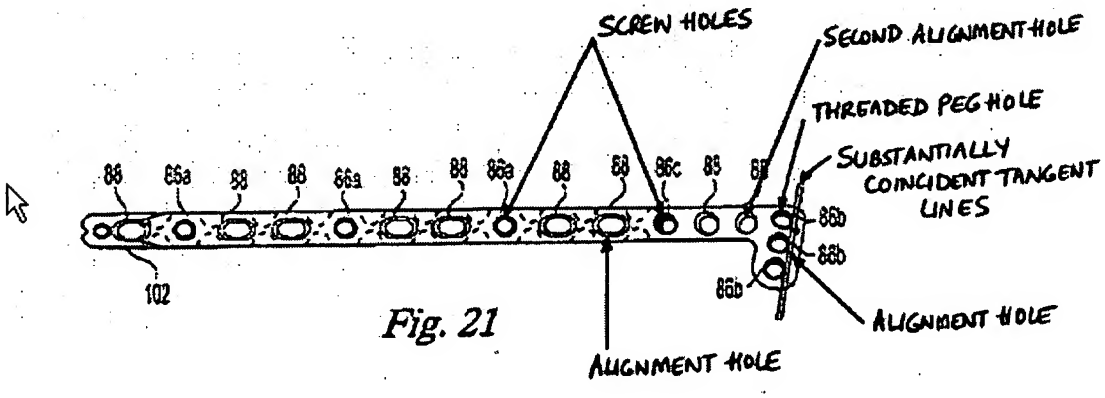
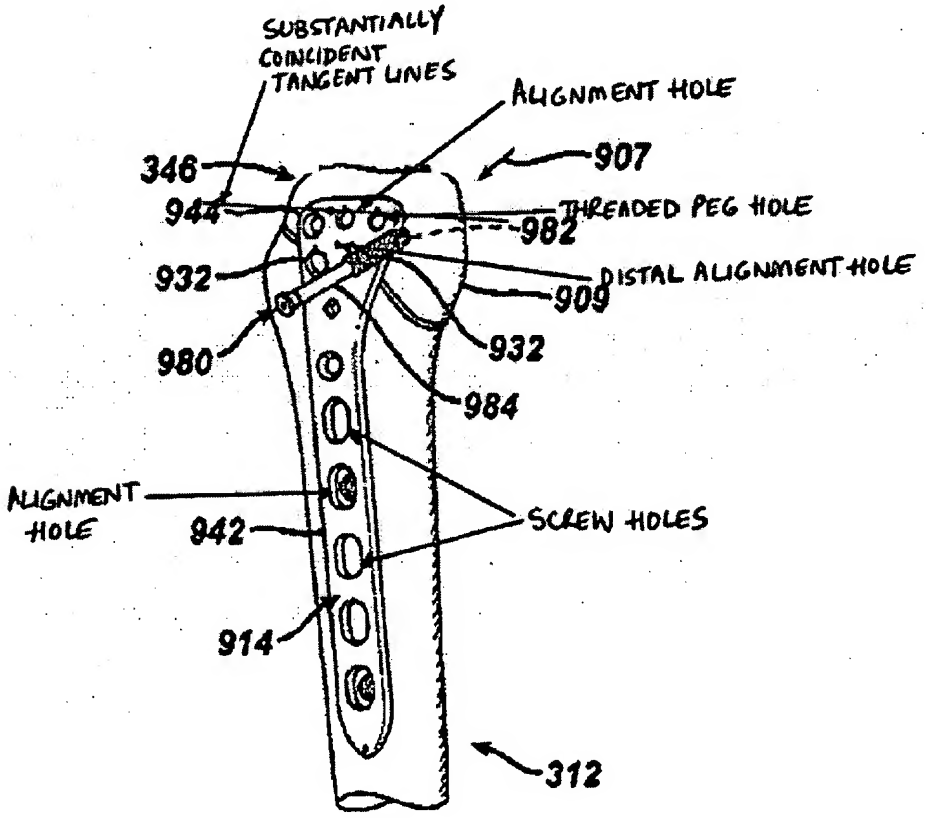


Fig. 21

Claims 37-38, 40-43, 45-46, 48-51, 53-55, 58-59 and 65-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Wack et al. (US 2004/0030339 A1).

Wack et al. disclose a plate 914 defining a first set of peg holes structurally adapted to engage a threaded head of a fixation peg and at least one non-threaded alignment hole 871 having a second relatively small diameter wherein the first alignment hole defines a tangent line substantially coincident with a line tangent to the first set of threaded (Figs. 20-22 and paras [0118]-[0162]). See a portion of Fig. 20 marked up to show features of Applicant's invention below.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wack et al. ((US 2004/0030339 A1) in view of Klaue et al. (US 5,002,544).

Wack et al. disclose all elements of the claimed invention except for the specific shape of the hole.

Klaue et al. teach providing a hole in a bone plate wherein the hole has a wider cross section toward the bone application side of the bone plate in order to permit the insertion and gliding of inclined screws or fixation members (Fig. 5 and col. 2, lines 59-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided holes having a cross section as taught by Klaue et al. in the bone plate of Wack et al. to permit the insertion and gliding of inclined fixation members.

The combination of Wack et al. and Klaue et al. discloses all elements of the claimed invention except for the shape of the hole at the upper surface of the bone plate being circular and the shape of the hole at the bottom surface of the bone plate being oblong. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the hole with the claimed cross sectional shapes at the upper and lower surfaces of the bone plate, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find

obvious for the purpose of providing a hole in a bone plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wack et al. ((US 2004/0030339 A1).

Wack et al. clearly disclose alignment holes 871 in the head portion of the bone plate (para [0139]).

It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to have provided n-1 alignment holes for n peg holes, since Applicant has not disclosed that providing a specific number of alignment holes between a specific number of peg holes provides an advantage. One of ordinary skill in the art, furthermore, would have expected the Wack et al. bone plate and applicant's invention, to perform equally well with either n+1 alignment holes for n peg holes or the claimed "n-1 alignment holes for n peg holes" because both numbers of alignment holes would perform the same function of provisionally fixing the plate to the bone.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. (US 6,623,486) in view of Klaue et al. (US 5,002,544).

Weaver et al. disclose all elements of the claimed invention except for the specific shape of the hole.

Klaue et al. teach providing a hole in a bone plate wherein the hole has a wider cross section toward the bone application side of the bone plate in order to permit the insertion and gliding of inclined screws or fixation members (Fig. 5 and col. 2, lines 59-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided holes having a cross section as taught by Klaue et al. in the bone plate of Weaver et al. to permit the insertion and gliding of inclined fixation members.

The combination of Weaver et al. and Klaue et al. discloses all elements of the claimed invention except for the shape of the hole at the upper surface of the bone plate being circular and the shape of the hole at the bottom surface of the bone plate being oblong. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the hole with the claimed cross sectional shapes at the upper and lower surfaces of the bone plate, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a hole in a bone plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. (US 6,623,486) in view of Putnam et al. (US 5,586,985).

Weaver et al. disclose all elements of the claimed invention except for the use of K-wires for provisional fixation of bone plate 80.

Putnam et al. teach the use of K-wires for provisional or temporary fixation of a bone plate to a bone surface (col. 7, lines 63-67 and col. 8, lines 1-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized K-wires as taught by Putnam et al. to temporarily fix the Weaver et al. bone plate to bone since it was well known in the art to use K-wires to temporarily or provisionally fix a bone plate to bone.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on October 10, 2007 have been fully considered but are not persuasive for the following reasons.

Contrary to Applicant's arguments with respect to claim 37 on page 13, the limitation "sized to closely receive the K-wire in a predetermined fixed axial orientation which is oblique relative to a bone contacting surface of said plate" only requires that the alignment hole be capable of receiving a K-wire that is inserted such that the K-wire is oblique to the bone contacting surface of the plate. Since the head portion of the Weaver et al. bone plate is angled relative to the bone surface, a K-wire inserted through the alignment hole would be oblique to the bone contacting surface of the plate. Regarding the limitation, distally displaced relative to a distal tangent line to the threaded holes," it is the Examiner's position that the alignment holes are proximally placed, i.e., "not displaced distally relative to a distal tangent line between two respective peg holes."

Regarding claim 48, Weaver et al. clearly disclose a shaft having a plurality of holes or "screw holes" with alignment holes (either 88 or 86a) that are configured to receive a K-wire that could be oblique relative to the bone contacting surface of the plate depending on the angle of insertion, i.e., predetermined fixed axial orientation.

Regarding claim 65, Putnam et al. teach the use of K-wires for bone plate fixation where distal purchase is not available for screws and provide the necessary motivation for using K-wires instead of bone screws.

Contrary to Applicant's arguments with respect to claim 37, Wack et al. clearly disclose alignment holes that are proximally placed, i.e., "not displaced distally relative to a distal tangent line between two respective peg holes."

Regarding K-wire holes 871, the Examiner notes that the hole(s) is(are) capable of receiving K-wire(s) in a predetermined fixed axial orientation, i.e., direction of

insertion chosen by the surgeon, such that the K-wire(s) are oblique to a bone-contacting surface of the plate due to the angled head of the bone plate.

The Examiner also notes that the limitation, "sized to closely receive the K-wire" only requires that the hole be capable of receiving an appropriately sized K-wire, a limitation that is met by Wack et al.

With regard to the rejections of claims 44 and 52 over Wack or Weaver in view of Klaue, the basis of the rejection is that the Applicant has not provided a criticality for why the upper opening must be circular. It is the Examiner's position that if the lower cross section of the hole is wider than the upper cross section of the hole, irrespective of the shapes of the upper and lower cross sections, the insertion and gliding of fixation members, such as screws or K-wires, is facilitated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
January 22, 2008

Anuradha Ramana

ANURADHA RAMANA
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700